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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/606,442 | 06/25/2003 | George Baran | 6298/431 | 2937 |

7590 09/27/2006

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| EXAMINER |
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HILL, LAURA C

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| ART UNIT | PAPER NUMBER |
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3761

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/606,442

Applicant(s)

BARAN, GEORGE

Examiner

Laura C. Hill

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 4-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 60-2503 *corrected page 4*

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments, see pages 7-10, filed 6 July 2006, with respect to the rejection(s) of claim(s) 64-65, 67, and 76-81 under Blake in view of Smith, claim 66 over Blake, Smith and Voucher, and claims 69-75 over Blake, Smith and Sheridan have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Baran (US 5,964,223).

Information Disclosure Statement

It is noted that the SU 185442 and SU812296 have been considered since they were submitted in parent application 09/265,603.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 77-81 and 64-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Baran (US 5,964,223). Regarding claim 77 Baran discloses a method of forming a nebulizing catheter 20 having closely spaced distal orifices 64, 88 (column 9, lines 30-32, column 12, lines 4-8 and lines 53-61) comprising providing a multilumen extruded polymer tubing (column 10, lines 24-26), heating a portion of the tubing to a transition temperature (column 10, lines 44-47), forming a j-shaped distal section

wherein the tubing curves away from a longitudinal axis of the catheter (figures 1-2); and forming a plurality of orifices 49, 64, 88 at the distal section of the tube, said orifices being sized to nebulize a liquid delivered through one of the lumens to form an aerosol with a gas delivered through another of said lumens (column 6, lines 62-column 7, line 12, column 11, lines 1-7).

Regarding claim 78 Baran discloses the plurality of orifices point towards a proximal end of catheter 20 (figures 3, 8 and 10).

Regarding claims 79-80 Baran discloses attaching a first end of a tether/wire 104 to an end of the distal section via a loop 106 and a second end to a portion of the catheter shaft (figures 6-7, column 13, lines 15-44).

Regarding claim 81 Baran discloses the catheter is constructed of a compliant/flexible material (column 9, lines 51-53).

Regarding claims 64-65 Baran discloses forming the orifices via cutting a distal end of the distal section and cutting the tubing to form a shaft portion of the catheter 20 (column 11, lines 1-3, figures 1-3, 8 and 10).

Regarding claim 66 Baran discloses exposing a portion of the tubing to high energy radiation (column 10, lines 39-43).

Regarding claim 67 Baran discloses the nebulizing catheter 10 is for use in the endotracheal tube 10 as part of the respiratory system (column 7, lines 25-32).

Regarding claim 68 Baran discloses heating the tubing to the glass transition temperature [i.e. the temperature between a melt and glass state] as discussed above with respect to claim 77.

Regarding claim 69-70 Baran discloses providing the nebulizing catheter with radiopaque markings 41 to facilitate positioning and placement (column 8, lines 45-46) that may be graduated along the catheter (column 8, lines 54-56).

Regarding claim 71 Baran discloses providing radiopaque markings by attaching radiopaque bands of metal and heat shrunk bands of doped radiopaque plastic to the catheter 20 (column 8, lines 46-52).

Regarding claims 72-75 Baran discloses providing ultrasonically reflected markings along the catheter forming a stripe with a coextrusion process, said strip formed by embedding a wire in the wall of the nebulization catheter (column 8, lines 56-65).

Regarding claim 76 see the discussion above with respect to claim 77.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (hours vary).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura C. Hill
Examiner
Art Unit 3761

LCH



TATYANA ZAMKAEVA
SUPERVISOR/TECHNICAL EXAMINER

